

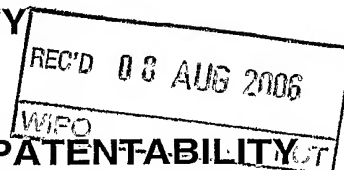
PATENT COOPERATION TREATY


PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference OFX069BWO		FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/EP2005/003395		International filing date (day/month/year) 31.03.2005	Priority date (day/month/year) 31.03.2004	
International Patent Classification (IPC) or national classification and IPC INV. A61B17/72				
Applicant ORTHOFIX INTERNATIONAL B.V. et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 11 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 1-6 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input checked="" type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 28.10.2005		Date of completion of this report 07.08.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Herberhold, C Telephone No. +49 89 2399-6042		



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2005/003395

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-23 as originally filed

Claims, Numbers

1-37 received on 01.02.2006 with letter of 25.01.2006

Drawings, Sheets

1/22-22/22 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☒ the claims, Nos. 19, 25-37 (as dependant of claim 1), 25-37 (as dependant on claim 16), 25-37 (as dependant on claim 19)
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2005/003395

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:
- ☐ restricted the claims.
 - ☒ paid additional fees.
 - ☐ paid additional fees under protest and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☐ neither restricted the claims nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-15, 16-18, 20-22
	No: Claims	
Inventive step (IS)	Yes: Claims	1-15, 16-18, 23, 24
	No: Claims	20-22
Industrial applicability (IA)	Yes: Claims	
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2005/003395

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/EP2005/003395

1 Reference is made to the following document:

D1: JP-A-10-57398
D2: FR-A-2 783 702
D3: FR-A-2 727 304
D4: US-A-5 702 215
D5: WO-A-03 007830
D6: US-A-6 575 973
D7: DE-A-3838388

2 Unity of invention, Rule 13, PCT:

This Authority considers that in the claims amended with letter of January 25th 2006 there are 3 inventions covered by the amended claims, indicated as follows:

- I: Claims 1-15, 25-37 directed to an intramedullary nail comprising a stem and a plurality of elements realized with at least a shape-memory material, the stem comprising at least two half-cylinders.
- II: Claims 16-18, 25-37 directed to an intramedullary nail comprising a stem and a plurality of elements realized with at least a shape memory material, each insert including a plurality of overlapped foils made by shape-memory material.
- III: Claims 19-24, 25-37: An intramedullary nail comprising a stem and a plurality of elements realised with at least a shape-memory material, the nail comprising a tubular jacket having a side wall which sheaths the stem and has the function of retaining the shape memory elements in the first shape when the nail is inserted in the bone.

The pre-characterizing portion of claim 1 corresponds to former claim 1. The subject-matter defined by the pre-characterizing portion of current claim 1 is not new over prior art document D1:

Document D1 discloses (the citations in parenthesis referring to that document) an Intramedullary nail (Fig. 2, 10, 11, No. 5) suitable for insertion in a fractured elongate

bone (Fig. 1), comprising a stem extending between a proximal end and a distal end, wherein the nail comprises a plurality of elements (No. 7b, 12b) realised with at least a shape-memory material (§16, 17), a plurality of seats (Nos. 2, 3, 5a) formed in the stem for housing said elements and in that said elements are suitable to take a first shape wherein they are retractably housed in the respective seats (Fig. 10) and a second shape wherein they project from the respective seats (Fig. 11, §18-20).

The pre-characterizing portion of claim 16 corresponds to former dependant claim 3 and is not new over D1 which additionally discloses Inserts, structurally independant from the stem comprising at least one of said shape-memory elements, suitable for insertion in a corresponding seat (Fig 11, Nos. 12b and 7b)

The pre-characterizing portion of present claim 19 is not new over D1 as outlined above.

The special technical features are thus to be found in the characterizing portions of the claims and have been used to label the above defined groups:

I: the stem comprises at least two half cylinders

II: the insert include a plurality of overlapped foils made by shape-memory material.

III: the nail comprises a tubular jacket having a side wall which sheaths the stem and has the function of retaining the shape memory elements in the first shape when the nail is inserted in the bone.

These features are obviously not the same nor corresponding (Rule 13.2).

Furthermore the groups identified above refer to the solution of very different technical problems:

Group I refers to the problem of including the shape memory elements within the stem and also that in conventional nails only limited size shape memory elements can be introduced into the stem.

Group II refers to the problem to better control the mechanical properties of the shape-memory insert.

Group III refers to the problem to keep the shape memory inserts safely hidden in the nail during insertion of the nail into the bone.

As the technical problem addressed in the different groups of inventions are different, the 3 groups are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT.

2.1 First group of inventions (Claims 1-15, 25-37):

2.1.1 Allowability of amendments:

The drawings of the first embodiments (Figs. 1-15) disclose the features of claims 1-15 in combination. In particular all "elements realised with at least a shape-memory material" are referred to as inserts and thus provide the technical effect of claim 1 as given in the description and in the letter of 25.1.06.

However, no support can be found in the description for the combination of the features of claims 25-37 with the feature "stem made of two united half-cylinders" of former claim 4. Said characteristic is disclosed for the embodiments of Figs. 1-15 only, no indication can be found in the application to apply the feature of the two united half-cylinders in combination with the features of the embodiments as depicted in Figs. 16-34.

Thus, for the first group of inventions, in accordance with Art. 34, PCT, no opinion as to novelty and inventive step can be given for claims 25-37.

2.1.2 Clarity, Art. 6 PCT:

Claim 1: In order to achieve the technical effect as defined in the description and the letter of 25.1.06 it appears essential (see the PCT-guidelines 5.33) that the "elements realised with at least a shape-memory material" are inserts structurally independent of the stem, because otherwise no insertion step takes place (the description discloses the inventive technical effect of the "stem realised of two half-cylinders" in

combination with structurally independant inserts only, see § 40 and §154,155) and the alleged technical effect is not present. The essential feature is defined e.g. in claim 3. For clarity reasons the features of claim 3 need to included into claim 1.

Dependant claims:

Claim 4: The feature that "each insert is inserted by pressure in the respective seat" is not clear. It cannot be decided from the finished product whether the insert has been inserted by pressure or not. Thus, this feature is non-limiting ("product-by process"-feature).

2.1.3 Novelty and Inventive step:

Claim 1: The features of the pre-characterizing portion are known from any of documents D1 (JP-A-10-57398), D2 (FR-A-2 783 702) or D3 (FR-A-2 727 304). The subject-matter of claim 1 differs from that prior art in that the stem comprises at least two half-cylinders united along the length. This results in an easier inclusion of the shape memory-elements into the stem during production. In particular, larger shape memory elements may thus be inserted. This solves problems and limits in the manufacturing process of the intramedullary nail.

None of the prior art documents discloses or suggests such a two-half cylinder construction.

Dependant claims:

As claim 1 (clarified by including the features of claim 3) is new and inventive over the prior art, all dependant claims are equally new and inventive.

2.1.4 Industrial applicability: Industrial applicability is obvious.

3 Second group of inventions (Claims 16-18, 25-37)

3.1 Allowability of amendments:

Claim 16 is a combination of the features of former claims 1,3, and 13. The subject-matter of claims 17 and 18 is supported by Fig. 13 and the description p.9, l. 4-7 and p. 10, l. 23-26.

However, no support can be found in the description for the combination of the features of claims 25-35 with the feature "insert including a plurality of overlapped foils made of shape memory material" of former claims 1, 3, and 13. Said characteristics are disclosed for the embodiments of Figs. 1-15 only, no indication can be found in the application to apply the feature of the "overlapped foils insert" in combination with the features of the embodiments as depicted in Figs. 16-34.

Thus, for the second group of inventions, in accordance with Art. 34, PCT, no opinion as to novelty and inventive step can be given for claims 25-37.

3.2 Novelty and inventive step:

Claim 16: Closest prior art is document D3 (FR-A-2 727 304) which discloses all the features of the pre-characterizing portion. The subject-matter of claim 16 differs from that prior art in that each insert includes a plurality of overlapped foils made by shape-memory material. The multiple foil design allows to choose the number of foils and the foil material in such a way as to control the mechanical properties of the insert thus solving the problem of adjustment of the mechanical properties of the insert to the particular bone of implant location. No prior art discloses or suggests such a multiple-foil construction for the inserts.

The subject-matter of claim 16 is thus new and inventive over the available prior art.

Dependant claims: As claim 16 is new and inventive, the dependant claims equally qualify the requirements of the PCT as to novelty and inventive step.

3.3 Industrial applicability: obviously present.

4 Third group of inventions (Claims 19-24, 25-37)

4.1 Allowability of amendments: Present claim 19 comprises the features of former

claims 1, 17 and 18, however, without the feature that the jacket comprises a plurality of transversal elongate holes made on the tubular wall. This feature is disclosed in the description as "characteristic of the invention" (description, p. 11, l. 25-32). Thus independant claim 19 is amended over the application as filed. As the independant claim is amended so are the dependant claims which do not comprises the indicated feature (claims 25-37). Thus novelty and inventive step will be evaluated for claims 20-24 only (please note that claim 20 includes the feature of the "plurality of transversal elongate holed made on the tubular wall". Thus the subject-matter of claim 20 and the claims dependant thereof is not amended over the application as filed.

4.2 Novelty and Inventive step of the dependant claims 20-24

4.2.1 Claim 20:

Document D1 discloses an intramedullary nail suitable for insertion in a fractured elongate bone comprising a stem (D1, Figs. 4-6, No. 7) extending between a proximal end and a distal end, a plurality of elements realised with at least a shape memory material (elements No. 7b, 12b) wherein said elements are suitable to take a first shape wherein they are retractably hosed in the respective seats (Fig. 10) and a second shape wherein they project from the respective seats (Fig. 11) wherein the nails comprises a tubular jacket (Fig. 2) having a side wall which sheathes the stem and has the function of retaining the shape memory elements in the first shape when the nail is inserted in the bone (Fig. 10). The side wall comprises a plurality of transversal elongate holes (Fig. 2, No. 5a) made on the tubular wall.

The subject-matter of claim 20 differs from that prior art in that a plurality of seats is formed in the stem for housing said elements, thus indicating that the elements are separate entities (as otherwise no seats would be required). Thus the stem may be made from a "normal" biocompatible metal, which solves the problem that shape memory materials are expensive. It is however known in the prior art (D2, p.5, l. 24-30) to provide just the spreading parts from the shape memory alloy in order to save costs. Therefore it appears obvious to the person skilled in the art to provide the

spreading elements as separate elements which are connected to the stem, the connection area qualifying as "seat". Therefore claim 20 is considered not inventive over the combination of D1 and D2.

Claims 21, 22: see D1, Fig. 10 and 11.

Claims 23, 24: None of the prior art discloses or suggests an axial shift of the stem controlled by means of rotation of a control screw. Please note that claim 23 should be dependant on claim 22 because the term "axial shift of the stem", (l. 14) defines that the shift relative to the jacket with respect to the stem occurs indeed along the axis of the nail.

Please further note that although the description formally discloses the jacket to be applicable for all embodiments, the description does not sufficiently disclose how to construct such a jacket for the embodiments depicted in Figs. 25-34 (Art. 5, PCT)